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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,832	03/28/2002	Takeshi Nagasu	082370-000000US	8651

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EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,832	NAGASU ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8 and 10-20* is/are pending in the application.

4a) Of the above claim(s) *10-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is written in response to applicant's correspondence submitted 2/2/04. Claims 1, 4, 5, and 6 have been amended and claims 2, 3, and 9 have been canceled. Claims 1, 4-8, and 10-20 are pending. Claims 10-20 are withdrawn from prosecution. Claims 1 and 4-8 are under prosecution herein. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. New rejections are set forth to address applicant's amendments to the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.**

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 4 is a method claim for the detection of a nucleic acid comprising nucleotides 36-1171 of SEQ ID NO: 1 which utilizes a step of hybridizing probes or primers that comprise portions of nucleotides 36-1171 of instant SEQ ID NO: 1. Because the claim is drawn using

"comprising" language to describe the primers and probes, the claim encompasses the use of and the detection of sequences that are not described herein, such as full length cDNA, genomic DNA, variants of many forms, nucleic acids from other species of animals, etc. Likewise, claim 5-8 utilize sequences that "specifically hybridize" to nucleotides 36-1171 of instant SEQ ID NO: 1, a genus of nucleic acids that contain sequences which are not described in the specification, such as full length cDNA, genomic DNA, variants of many forms, nucleic acids from other species of animals, etc.

The large genus of nucleic acids utilized in these methods is represented in the specification by a nucleic acid consisting of instant SEQ ID NO: 1 and nucleic acid fragments consisting of portions of SEQ ID NO: 1. Thus, applicant has express possession of only one species in a genus which comprises many, many different possibilities. The present claims encompass the use and detection of full-length genes and cDNAs that are not fully described, other than that they contain or hybridize to instant SEQ ID NO: 1 which is a partial cDNA. There is substantial variability among the species of nucleic acid molecules encompassed within the scope of the claims because SEQ ID NO: 1 is only a fragment of any full-length gene or cDNA species. The partial cDNA provided herein does not include a disclosure of an open reading frame of which it is a part is not representative of the genus of cDNAs and genes encompassed by the claims because no information regarding the coding capacity of the any cDNA molecule is disclosed. Since the claimed genus encompasses genes yet to be discovered, the disclosed structural feature does not constitute a substantial portion of the claimed genus.

With regard to the written description, all of these claims encompass nucleic acid sequences or methods which utilize nucleic acid sequences different from those disclosed in the

specific SEQ ID No:s which, for claims 5-8 include modifications allowed by the hybridization language for which no written description is provided in the specification.

It is noted that in Fiers v. Sugano (25 USPQ2d; 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only a nucleic acid consisting of instant SEQ ID NO: 1 and nucleic acids consisting of fragments of instant SEQ ID NO: 1 are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

Weighing all factors, including the partial structure of the DNAs that comprise or hybridize to SEQ ID NO: 1, the breadth of the claims as reading on any number of undescribed nucleic acids, and the lack of correlation between the structure and function of the genes and cDNAs that are not described, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DNAs which comprise SEQ ID NO: 1 or which hybridize to SEQ ID NO: 1, as encompassed by and/or used in the instant product and method claims.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite because it recites a preamble that sets forth a method for detecting the nucleic acid molecule comprising nucleotides 36-1171 of SEQ ID NO: 1, but the single method steps requires only that the method utilize portions of SEQ ID NO: 1 to hybridize to or amplify a sample, and then that the hybridization or amplification are detected. Thus, it is not clear from the recitation of the claim how or if the preamble breathes life and meaning into the claim, as the claim does not recite a positive process step that results in the detection of SEQ ID NO: 1 in particular. It is not clear if applicant intends to claim any method that uses a DNA that is a portion of at least 15 nucleotides of the recited fragment of SEQ ID NO: 1, and therefore any method that utilizes a DNA comprises a 15mer fragment of nucleotides 36-1171 of SEQ ID NO: 1 under any stringency conditions would be encompassed within the claim, or if applicant intends to claim a method wherein SEQ ID NO: 1 is positively detected (for which no method step exists in the instant claim). Clarification is required.

Claims 5-9 are further indefinite over the recitation of a "normal" level of cedar pollen specific IgE because "normal" is a relative term for which no basis for judgment is given. That is, what population is the "normal" to be measured against?

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Koch (US6610481).

Koch *et al.* teach an isolated nucleic acid molecule consisting of a fragment of nucleotides 36-1171 of instant SEQ ID NO: 1 that is at least 15 nucleotides long. Specifically, Koch *et al.* teach their instant SEQ ID NO: 8 which is a 28 base nucleic acid that is identical to nucleotides 429-456 of instant SEQ ID NO: 1. Thus, the nucleic acid taught by Koch *et al.* meets the limitations of instant claim 1.

Claim Rejections - 35 USC § 112

Claims 1 and 4-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen , 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

In the instantly rejected claims, the new limitation of "nucleotides 36-1171 of SEQ ID NO: 1" in claims 1 and 4-8 appears to represent new matter. The remarks filed with the amendment state that the first 35 nucleotides of SEQ ID NO: 1 correspond to a primer and adaptor sequences used in the isolation of SEQ ID NO: 1, and cites a portion of the specification that states "the adaptor primer" provided in a Marathon cDNA Amplification kit was used." However, this is not sufficient to provide basis for the newly added range. The specification does not identify the length of the adaptor primer. The two adaptor primers taught in the user

manual provided by applicant are a 27 and 23 base pairs long. It is not clear from the teachings of the specification that nucleotides 1-35 of SEQ ID NO: 1 are the "adaptor primer" referred to in the specification. Therefore the claims are rejected as containing new matter.

Response to Remarks

Applicant argues that there is a strong presumption that the method claims presented herein meet the written description requirement. Perhaps there is a strong presumption, however in the instant case, for the reasons given in the rejection it is concluded that the presumption is overcome and the claims lack written description. The claims encompass the use of a wide variety of molecules of which applicant was not in possession at the time the invention was filed, up to and including the full length cDNA sequence of which SEQ ID NO: 1 is a fragment, but also including, due to the breadth of the "specifically hybridizes" language of claims 5-8 fragments that comprise portions of sequences other than SEQ ID NO: 1 including allelic and splice variants, as well as related genes from other organisms, etc. These sequences are an essential feature of the claimed invention as they are necessary for the practice of the hybridization assays recited therein. Applicants state that the claimed invention meets the standard set forth in Lily, however the examiner does not agree. In Lily a nucleic acid sequence from one species of animal (mouse) was disclosed, and applicant was claiming a nucleic acid sequence from another species (human). The court ruled against such a claim as provided adequate written description of the claimed sequence was not provided. In this case, applicants have disclosed a single sequence and have provided claims which encompass a broad spectrum of additional sequences which are not provided.

Applicant argues that the analysis of a method claim differs from a composition claim because additional flanking sequences are not essential to practice of a hybridization method. However, the examiner disagrees and applies the Written Description guidelines as cited in applicant's arguments. The practice of this method includes the use of a probe "comprising" portions of SEQ ID NO: 1 or that hybridize to portions of SEQ ID NO: 1, and as noted, these claims include the use of a wide variety of fragments and probes that are not described in the specification. Claims 5-8 do not even require that particular portions of SEQ ID NO: 1 are present, only that the sequence "specifically hybridize to nucleotides 36-1171," and this can include any probe of any length that can hybridize. The probe used in the methods of claims 4-8 is an essential feature of the claims, and therefore adequate written description must be provided for the probe. The rejection is maintained.

The rejection of claim 4 under 112 2nd paragraph is reiterated because although additional method steps have been added, the claim still does not recite how the amplification or hybridization relate to the preamble of the claim which recites the detection of a particular nucleic acid.

Conclusion

7. A nucleic acid consisting of nucleotides 36-1171 of SEQ ID NO: 1 is free of the prior art. Further, the prior art does not teach or suggest that instant SEQ ID NO: 1 is differentially expressed in T-cells in response to cedar pollen allergy.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached by calling (571) 272-0782.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

JEFFREY FREDMAN
PRIMARY EXAMINER

Juliet C Switzer
Examiner
Art Unit 1634

April 13, 2004